Case: 1:17-md-02804-DAP Doc #: 4036-5 Filed: 10/18/21 1 of 9. PageID #: 5449 (SEN-00196) DATE: 02/03/2003 4:03 PM

ACTION: No Change

Prospective drug utilization review. 4729-5-20

- (A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:
  - (1) Over-utilization or under-utilization;
  - (2) Therapeutic duplication;
  - (3) Drug-disease state contraindications;
  - (4) Drug-drug interactions;
  - (5) Incorrect drug dosage;
  - (6) Drug-allergy interactions;
  - (7) Abuse/misuse;
  - (8) Inappropriate duration of drug treatment;
  - (9) Documented food-nutritional supplements-drug interaction.
- (B) Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include consulting with the prescriber and/or counseling the patient.
- (C) Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:
  - (1) Peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);
  - (2) American hospital formulary service drug information;
  - (3) United States pharmacopoeia drug information;
  - (4) American medical association evaluations.

PLAINTIFFS TRIAL **EXHIBIT** 

print date: 62/03/2003 09:03 PM

R.C. 119.032 review dates: 02/03/2003 and 02/01/2007

CERTIFIED ELECTRONICALLY

Certification

02/03/2003

Date

Promulgated Under: 119.03 Statutory Authority: 4729.26 Rule Amplifies: 4729.26

Prior Effective Dates: 9/10/1976, 9/1/1985,

3/1/1993, 2/1/1998

Case: 1:17-md-02804-DAP Doc #: 4036-5 Filed: 10/18/21 3 of 9 PageID #: 5449PtGEN-00196

ACTION: Final DATE: 10/17/2011 3:42 PM

4729-5-20 **Prospective drug utilization review.** 

(A) Prior to dispensing any prescripti	on, a pharmacist	shall review the	e patient prof	file for
the purpose of identifying:				

- (1) Over-utilization or under-utilization;
- (2) Therapeutic duplication;
- (3) Drug-disease state contraindications;
- (4) Drug-drug interactions;
- (5) Incorrect drug dosage;
- (6) Drug-allergy interactions;
- (7) Abuse/misuse;
- (8) Inappropriate duration of drug treatment;
- (9) Food-nutritional supplements-drug interactions.
- (B) Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing an OARRS report or another state's report if applicable and available, and/or consulting with the prescriber and/or counseling the patient.
- (C) Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:
  - (1) Peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);
  - (2) American hospital formulary service drug information;
  - (3) United States pharmacopoeia drug information;
  - (4) American medical association evaluations.

print date: 10/17/2011 89:02 PM

(D) Prior to dispensing a prescription, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period and/or another state's report, where applicable and available, if a pharmacist becomes aware of a person currently:

- (1) Receiving reported drugs from multiple prescribers;
- (2) Receiving reported drugs for more than twelve consecutive weeks;
- (3) Abusing or misusing reported drugs (i.e. over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks):
- (4) Requesting the dispensing of reported drugs from a prescription issued by a prescriber with whom the pharmacist is unfamiliar (i.e. prescriber is located out-of-state or prescriber is outside the usual pharmacy geographic prescriber care area); or.
- (5) Presenting a prescription for reported drugs when the patient resides outside the usual pharmacy geographic patient population.

After obtaining an initial OARRS report on a patient, a pharmacist shall use professional judgment based on prevailing standards of practice in deciding the frequency of requesting and reviewing further OARRS reports and/or other states' reports for that patient.

In the rare event a report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving and reviewing a report.

Effective: 10/27/2011

R.C. 119.032 review dates: 08/10/2011 and 10/01/2016

CERTIFIED ELECTRONICALLY

Certification

10/17/2011

Date

Promulgated Under: 119.03 Statutory Authority: 4729.26

Rule Amplifies: 4729.26

Prior Effective Dates: 9/10/76, 9/1/85, 3/1/93, 2/1/98, 3/1/99, 4/27/07

Case: 1:17-md-02804-DAP Doc #: 4036-5 Filed: 10/18/21 6 of 9 PageID #: 5449P&EN-00196 DATE: 11/05/2015 4:33 PM

**ACTION:** Final

4729-5-20

Prospective drug utilization review.

- (A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:
  - (1) Over-utilization or under-utilization;
  - (2) Therapeutic duplication;
  - (3) Drug-disease state contraindications;
  - (4) Drug-drug interactions;
  - (5) Incorrect drug dosage;
  - (6) Drug-allergy interactions;
  - (7) Abuse/misuse;
  - (8) Inappropriate duration of drug treatment;
  - (9) Food-nutritional supplements-drug interactions.
- (B) Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing an OARRS report or another state's report. pursuant to paragraph (D) of this rule, if applicable and available, and/or consulting with the prescriber and/or counseling the patient.
- (C) Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:
  - (1) Peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);
  - (2) American hospital formulary service drug information;
  - (3) United States pharmacopoeia drug information;
  - (4) American medical association evaluations.

orini date: 11/05/2015/09:12 PM

(D) Prior to dispensing an outpatient prescription for a reported drug as listed in rule 4729-37-02 of the Ohio Administrative Code, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period, including a border state's information when the pharmacist is practicing in a county bordering another state if that state's information is available, in any of the following circumstances:

- (1) A patient adds a different or new reported drug to their therapy that was not previously included;
- (2) An OARRS report has not been reviewed for that patient during the preceding 12 months, as indicated in the patient profile;
- (3) A prescriber is located outside the usual pharmacy geographic area:
- (4) A patient is from outside the usual pharmacy geographic area:
- (5) A pharmacist has reason to believe the patient has received prescriptions for reported drugs from more than one prescriber in the preceding 3 months, unless the prescriptions are from prescribers who practice at the same physical location:
- (6) Patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks.
- (E) In the rare event a report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving and reviewing a report.
- (F) A pharmacist may use a delegate to request an OARRS report.
- (G) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. Based upon information obtained during prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about the legitimacy of a prescription. A pharmacist is not required to dispense a prescription of doubtful, questionable, or suspicious origin.
- (D) Prior to dispensing a prescription, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period and/or another state's report, where applicable and available, if a pharmacist becomes aware of a

## person currently:

- (1) Receiving reported drugs from multiple prescribers;
- (2) Receiving reported drugs for more than twelve consecutive weeks;
- (3) Abusing or misusing reported drugs (i.e. over-utilization, early refills, appears overly sedated or intexicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks);
- (4) Requesting the dispensing of reported drugs from a prescription issued by a prescriber with whom the pharmacist is unfamiliar (i.e. prescriber is located out of state or prescriber is outside the usual pharmacy geographic prescriber care area); or.
- (5) Presenting a prescription for reported drugs when the patient resides outside the usual pharmacy geographic patient population.

After obtaining an initial OARRS report on a patient, a pharmacist shall use professional judgment based on prevailing standards of practice in deciding the frequency of requesting and reviewing further OARRS reports and/or other states' reports for that patient.

In the rare event a report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving and reviewing a report.

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Effective:

02/01/2016

Five Year Review (FYR) Dates:

10/01/2016

CERTIFIED ELECTRONICALLY

Certification

11/05/2015

Date

Promulgated Under:

Statutory Authority:

Rule Amplifies: Prior Effective Dates: 119.03

4729.26

4729.26

9/10/76, 9/1/85, 3/1/93, 2/1/98, 3/1/99, 4/27/07,

10/27/11